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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,266	03/17/2005	Giuseppe Alvaro	PI4749U/SW	9337

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

03/31/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/502,266

**Applicant(s)**

ALVARO ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11, 15 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11, 15, 25, 26 and 28 is/are allowed.
- 6) ☒ Claim(s) 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 11, 15, 25-26 and 28 in the reply filed on Dec. 13, 2007 is acknowledged.

Claims 1-10, 12-14, , 16-24 have been canceled. Claims 11, 15, 25-28 are pending.

2. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). As stated in the MPEP 2164.01(a) "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". The analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407. The factors to be considered herein are those set forth as the *In re Wands*, 8 USPQ 2<sup>nd</sup> 1400 (1988) decision.

The analysis is applied to the instant case.

#### Nature of invention

The claim is drawn to employing the claimed compounds for treating unlimited disorders of depressive states, anxiety, sleep disorder, schizophrenic disorders, emesis, inflammatory diseases or the bladder and or gastrointestinal disorders.

#### The state of the art and predictability

Each disorder encompassed by the above listing is a disorder of different etiology for which therapeutic efficacy can be achieved if intervention against the etiology or symptom can be made. The instant compounds was described to have neurokinin antagonistic activity. There are many specific neurokinin receptors for which structural specific compounds can be effective

as intervention in mechanism resulting in treatment of disease or symptoms. For example, the US 5,654,316 disclosed 4-hydroxy, 4-phenyl gem disubstituted piperidines having neurokinin A antagonistic activity for treating bladder contraction; US 6,479,518 disclosed cyclopantyl zwitter compounds having NK1R antagonistic activity for treating anxiety; US 2005/0090534 disclosed oxazolyl compounds having NK1/NK3 antagonistic activity for treating schizophrenia. There has not been found any umbrella structure which binds all neurokinin receptor of any sub-type and be active in all neurokinin activity.

Structurally similar compounds were known to treat pain, migraine, emesis or inflammation (see CA 124 or CA 131).

*The amount of guidance and working examples*

In the specification, on page 59 it was described that the affinity of the compound of the invention for NK1 receptor was determined using the NK1 receptor binding affinity method measuring in vitro by the compounds' ability to displace [3I-1] - substance P (SP) from recombinant human NK1 receptors expressed in Chinese Hamster Ovary (CHO) cell membranes. The affinity values are expressed as negative logarithm of the inhibition constant (Ki) of displacer ligands (pKi). The pKi values obtained as the average of at least two determinations with representative compounds of the invention are within the range of 8.24 to 10.21.

There provided no nexus in the record what efficacy does this in vitro binding activity would be therapeutically against what disorder.

3. Claims 11, 15, 25-26 and 28 are allowable. The claimed compounds are disclosed in US 2005/0239829 (compare CA139 and CA 140) which is not prior art because the reference has a later filing date. The reference although disclosed the compounds but has demarcated its claims from the instant claims by limiting the R1 to substituted hydroxyl moiety.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*

*/Celia Chang/  
Primary Examiner  
Art Unit 1625*